

REMARKS/ARGUMENTS

Status of the Claims

Claim 9 has been canceled and claims 1-8 have been amended. Claims 1-8 are pending with claim 1 being the independent claim. No new matter has been added by this amendment. Reconsideration and allowance of this Application are respectfully requested.

Double Patenting Rejection

In the Office Action dated July 14, 2008, claims 1-9 were rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,905,477 to McDonnell *et al.* ("McDonnell") in view of U.S. Patent No. 5,242,430 to Arenas *et al.* ("Arenas"). The analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection (MPEP 804.II.B.1). Accordingly, Applicants respectfully traverse this rejection as follows.

Claim 1 of the instant application, as amended, recites a catheter and guide wire exchange system that includes, *inter alia*,

a guide member slidably mounted on the proximal shaft and having an outer member and an inner member, the inner member having a catheter passageway extending there through for slidably receiving the catheter shaft . . .
the outer member being selectively rotatable relative to and around the inner member.

The claimed system requires that the guide member, including both the inner and outer members, be slidable along the proximal catheter shaft.

McDonnell's guide member (102) is slidable along proximal catheter shaft (112). Applicants agree with the characterization in the rejection at ¶1, p. 3 that Arenas' rotatable portion (14) of handle (10) is provided for rotationally steering catheter (22). However, Arenas discloses that a strong, frictional attachment is required between handle (10) and catheter (22). "Such attachment [which] is sufficient to rotationally affix the catheter to grip member (14) . . ." Arenas C4: L65-C5: L14. Therefore, the combination of McDonnell and Arenas, as proposed in the rejection, would entail a "strong attachment" between a rotatable outer handle member and the catheter shaft. Such an attachment would prevent the sliding operation of the modified handle along the catheter shaft of McDonnell, thereby making the catheter unsuitable for its intended purpose. *See* MPEP §2143.01 ("If proposed modification would render the prior art

invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” *Citing In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

In view of the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the Office Action, because there is no objective reason to combine Arenas and McDonnell in the manner asserted by the Office Action, and because such a combination would make the device of McDonnell unsuitable for its intended purpose. Claims 2-8 depend from claim 1 and include additional advantageous features, and are patentable for the same reasons over McDonnell or Arenas, taken either alone or in combination. The cancellation of claim 9 renders its rejection moot. Whereas Claims 1-8 are not obvious under 35 U.S.C. 103(a) over claims 1 and 2 of McDonnell in view of Arenas, the rejection under non-statutory obviousness-type double patenting is improper, and Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §103 Rejections

In the Office Action, claims 1-5, 8, and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,334,187 to Fischell *et al.* (“Fischell”) in view of Arenas. In ¶6, the rejection argues that it would have been obvious to modify Fischell by providing the rotatable handle of Arenas to make it easier for the user to hold and steer the catheter through tortuous vasculature. Applicants respectfully traverse this rejection on grounds similar to those explained above with respect to the proposed obvious combination of McDonnell and Arenas.

Like McDonnell, Fischell’s handle (30) is slidable along catheter shaft (20), as mentioned in the rejection at ¶1.d, p. 3, citing Fischell C4: L35-C6: L20. However, Arenas discloses that a strong, frictional attachment is required between handle (10) and catheter (22). Therefore, the combination of Fischell and Arenas, as proposed in the rejection, would entail a “strong attachment” between a rotatable outer handle member and the catheter shaft. Such an attachment would prevent the sliding operation of the modified handle along the catheter shaft of Fischell, thereby making the catheter unsuitable for its intended purpose.

In view of the foregoing, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the Office Action because there is no objective reason to combine Arenas and Fischell in the manner asserted by the Office Action, and because such a combination would make the device of Fischell unsuitable for its intended purpose. Claims 2-5

and 8 depend from claim 1 and include additional advantageous features and are patentable for the same reasons over Fischell or Arenas, taken either alone or in combination. The cancellation of claim 9 renders its rejection moot. Applicants respectfully request that the rejection of claims 1-5 and 8 be withdrawn.

In the Office Action, claims 6 and 7¹ were rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of Arenas, and further in view of U.S. Patent No. 5,250,036 to Farivar ("Farivar"). Applicants respectfully traverse this rejection.

Claims 6 and 7 depend directly or indirectly from claim 1 and are patentable for the same reasons over the combination of Fischell and Arenas, as explained above. Farivar fails to disclose the elements missing from Fischell and Arenas that would be required to render the proposed combination obvious.

Conclusion

For the foregoing reasons, Applicants believe all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone number 978.739.3075 (Eastern Time).

Respectfully submitted,

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¹ Although the Office Action is silent as to which claims were actually rejected under this rejection, Applicant assumes that claims 6 and 7 were rejected in view of the language of the claims being addressed in ¶7.